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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,009	05/03/2005	Ruth Chiquet-Ehrismann	1-32411A/FMI	1199
1095	7590	02/20/2007	EXAMINER	
NOVARTIS			GUSSOW, ANNE	
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 104/3			ART UNIT	
EAST HANOVER, NJ 07936-1080			PAPER NUMBER	
			1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/509,009

Applicant(s)

CHIQUET-EHRISMANN ET AL.

Examiner

Anne M. Gussow

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 14-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date February 11, 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: specification pages 3-4 and sequence alignment.

DETAILED ACTION

1. Applicant's election of Group VI, claims 11-13, drawn to an antibody that recognizes SEQ ID No. 4, in the reply filed on December 22, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-10 and 14-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 22, 2006.

3. Claims 11-13 are under examination.

Specification

4. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the specification contains areas on each page where the text is unreadable, see attached example of pages 3-4.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject

matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

5. The disclosure is objected to because of the following informalities: there are typographical errors, for example on page 8 line 15 "assays" should read assay and on page 36 line 23 "iin" should be in.

Appropriate correction is required throughout.

Claim Objections

6. Claims 11 and 13 are objected to because of the following informalities: the claims are drawn in part, to a non-elected invention of an antibody that recognizes the polypeptide have the amino acid sequence of SEQ ID No. 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1643

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite an antibody that specifically recognizes tenascin W for use as a pharmaceutical. It is unclear what the "use" is, is it as a treatment or as a method of making a pharmaceutical.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 11-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 11-13, as written, do not sufficiently distinguish over antibodies as they exists naturally because claims 11-13 do not particularly point out any non-naturally occurring differences between the claimed antibodies and binding compositions and the structure of naturally occurring antibodies.

In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193

Art Unit: 1643

(1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)).

However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" antibody or similar language would obviate this rejection.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni, et al. (US Pat. Appl Pub 2002/0151009, October 17, 2002, filed August 28, 2001, as cited in previous action).

The claims are drawn to an antibody that specifically recognizes tenascin W having the amino acid sequence of SEQ ID No. 4.

Ni, et al. teach antibodies that bind to a human protein homologous to the tenascin W protein (page 15 paragraphs 178-180 and table 1, clone 13, SEQ ID No. 29). Since the tenascin W protein of Ni shares homology with the tenascin W protein of

SEQ ID No. 4 (see sequence alignment), one would readily envisage the antibody of Ni would bind SEQ ID No. 4.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/509,009

Page 7

Art Unit: 1643

Anne M. Gussow, Ph.D.

February 6, 2007

A handwritten signature in black ink, appearing to be 'L. Helms', written above the printed name.

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

IntelliGenetics

FastDB - Fast Pairwise Comparison of Sequences

Release 5.4

Results file us-10-509-009-4.res made by bshears on Thu 8 Feb 107 16:54:14-PST.

```
Query sequence being compared: US-10-509-009-4 (1-1294)
Number of sequences searched: 1
Number of scores above cutoff: 1
```

Results of the initial comparison of US-10-509-009-4 (1-1294) with
File : /home/bshears/feb8/gussow939*

Subject	Score
N	100
U	50
M	50
B	50
E	50
R	50
O	50
F	50
S	50
E	50
Q	50
U	50
E	50
N	50
C	50
E	50

PARAMETERS

	Unary	K-tuple
Similarity matrix	1	2
Mismatch penalty	1.00	20
Gap penalty	0.05	32
Gap size penalty	0	
Cutoff score	0	
Randomization group		

SEARCH STATISTICS

Scores:	Mean	Median	Standard Deviation
	84	0	0.00
Times:	CPU	Total Elapsed	
	00:00:00.00	00:00:00.00	

```

Number of residues:      87
Number of sequences searched: 1
Number of scores above cutoff: 1

```

The scores below are sorted by initial score. Significance is calculated based on initial score.

A 100% identical sequence to the query sequence was not found

The list of best scores is:

Sequence Name	Description	Length	Score	Init. Opt.	Sig.	Frame
1. US-09-939-825-29	Sequence 29, Application	87	84	84	0.00	0

1. US-10-509-009-4 (1-1294)
US-09-939-825-29 Sequence 29, Application US/09939825

Sequence 29, Application US/09939825
GENERAL INFORMATION:

APPLICANT: NI et al.

FILE OF INVENTION: F1040612
FILE REFERENCE: Human Polyt

FILE REFERENCE: Human Polynucleotides, Polypeptides, and Antibodies
CURRENT APPLICATION NUMBER: US/09/939, 825

CURRENT FILING DATE: 2001-08-28

PRIOR APPLICATION NUMBER: PCI/US01/05498
PRIOR FILING DATE: 2001-03-23

PRIOR APPLICATION NUMBER: 60/184,664

PRIOR FILING DATE: 2000-02-24

PRIOR APPLICATION NUMBER: 60/189,874
 PRIOR FILING DATE: 2000-03-16

NUMBER OF SEO ID NOS: 35

SOFTWARE: PatentIn Ver. 2.0

SEQ ID NO 29

LENGTH: 87
TYPE: PBT

ORGANISM: *Homo sapiens*

1

Initial Score	=	84	Optimized Score	=	84	Significance	=	0.00
Residue Identity	=	96%	Matches	=	84	Mismatches	=	3
Gaps	=	0	Conservative Substitutions	=			=	0

1160 1170 1180 1190 1200 1210 1220
 DQGTNESAYVLYIFVQVASKERYKLTGKRYGTAGDALTYTHNGKFTTPRRNDIALSNALTHHGGWMM
 ARGNDIALSNALTHHGGWMM
 X 10 20

[illegible]